

Application Serial No. 10/676,408  
Filed October 1, 2003  
Applicant Gilbert Rene Gonzales et al.  
Amendment dated March 10, 2008  
Confirmation No. 8069  
Attorney Docket No. PEDI-13

## **REMARKS**

Following this response, claims 27-36 and 47-50 are pending in this application. Claims 1-26, 37-26, and 51 have been withdrawn by the Examiner. Claims 27-36 and 47-50 presently stand rejected. Claims 27 and 47 are presently amended. In view of these amendments and the discussion below, it is submitted that the application is now in condition for allowance.

### **Claim Rejections 35 U.S.C. § 102**

The Examiner has maintained the rejection of claims 27-36 and 47-50 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,687,662 (Schobel). In particular, the Examiner points to column 3, lines 10-12, and the abstract of Schobel, and states that Schobel discloses a method for oral administration of an effervescent composition in the form of tablets or powders including a therapeutic agent, a granulating agent, a microparticulate effervescent component and an effervescent system that dissolve rapidly in water to yield an effervescent solution containing a completely dissolved therapeutic agent. The Examiner further states that the granulating agent of Schobel causes slow disintegration of the therapeutic agent and release of gas (citing column 4, lines 17-28), and that the effervescent system includes compounds capable of reacting with carbonate containing materials to cause the release of carbon dioxide when contacted with sufficient water (citing column 5, lines 14-18 and lines 45 et seq.). Applicants respectfully disagree.

As an initial matter, Applicants note that independent claims 27 and 47 (the only independent claims presently being examined) as presently amended each require a solid ingestible pharmaceutical composition having "a gas-dispersing component including a solid matrix having at least one interior space with at least one first gas contained therein." Support for these amendments may be found at least at paragraph [0024] of the present application. Applicants submit that Schobel does not disclose a gas-dispersing component including a solid matrix having at least one interior space with at least one first gas contained therein.

As described at column 2, lines 20-27, the composition of Schobel includes (1) a preblended mixture of (a) a granulated therapeutic agent and (b) a component of an effervescent system; and (2) other components of the effervescent system. In the preblended mixture, the granulated therapeutic agent and the component of the effervescent system (which is described in Schobel as being a "microparticulate acid") are of roughly similar size (the granulated therapeutic agent being between 100-600 microns and the microparticulate acid being 50-600 microns).

The "microparticulate acids," described in Schobel, are capable of reacting with carbonate-containing materials to cause the release of carbon dioxide when contacted with a sufficient amount of water. As described above, in Schobel, a granulated therapeutic agent (of 100-600 microns) and microparticulate acids (of 50-600 microns) are admixed to form a preblended mixture. The microparticulate acids are one

component of the effervescent system. The remainder of the effervescent system includes all the ingredients of a rapid-dissolving effervescent composition, except for the microparticulate acids as stated at column 5, lines 43-45. And in particular, at column 5, lines 45-64, Schobel describes that the remainder of that effervescent system uses carbonate-containing materials. The various components of the Schobel composition (the preblended mixture of therapeutic agent and microparticulate acid, and the carbonate-containing materials of the remainder of the effervescent system) can then be formed into a desirable shape, such as a tablet, to render a final product.

In use, this tablet is added to an aqueous environment (such as water), causing the microparticulate acids to react with the carbonate-containing materials to release carbon dioxide. Nowhere in Schobel is any other gas explicitly disclosed. Further, Schobel does not disclose a solid matrix having at least one interior space with at least one first gas contained therein. Applicants thus submit that Schobel does not disclose a solid ingestible pharmaceutical composition including "a gas-dispersing component including a solid matrix having at least one first gas contained therein," as is recited in independent claims 27 and 47 of the present application. As such, Applicants respectfully assert that Schobel does not anticipate independent claims 27 or 47 (or any of their dependent claims 28-36 and 48-50).

The Examiner has further maintained the rejection of claims 27-36 and 47-50 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,223,264

(Wehling). The Examiner states that Wehling discloses a method for oral administration of oral effervescent dosage forms including a mixture of at least one effervescent disintegrating agent, and a pediatrically effective amount of at least one intended ingredient in the form of a tablet. The Examiner further states that the effervescent agent of Wehling includes compounds that evolve gas by means of chemical reactions, which takes place upon exposure of the effervescent agent to produce carbon dioxide, oxygen, or other gases upon contact with water including saliva or simple gastric fluids. Applicants respectfully disagree.

Like Schobel, Applicants submit that Wehling also does not disclose "a gas-dispersing component including a solid matrix having at least one interior space with at least one first gas contained therein," as is recited in independent claims 27 and 47 of the present application. Like Schobel, Wehling simply discloses an effervescent formulation including a medicament in tablet form, wherein that tablet also includes effervescing components. In particular, Wehling includes "effervescent disintegration agents," which include compounds that evolve a gas. As described at column 3, lines 10-17 of Wehling, the effervescent disintegration agent includes one acid and at least one base, the base being selected from the group consisting of carbonate salts, bicarbonate salts, and mixtures thereof. The acids and bases of the effervescent disintegration agent are water-activated materials. And thus, the composition of Wehling may be provided in a tablet form and added to an aqueous vehicle, such as

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water. When the tablet contacts the water, the acids and bases of the effervescent disintegration agents react to produce carbon dioxide gas. At column 5, lines 38-42, Wehling allows that an alternate gas, such as oxygen, can be evolved from reactants of the effervescent disintegration agents. However, nowhere does Wehling teach or suggest a gas-dispersing component including a solid matrix having at least one interior space with at least one first gas contained therein. Such a solid matrix and first gas is recited in both independent claims 27 and 47, and thus all of their dependent claims. As such, Wehling does not anticipate either claim 27 (or its dependent claims 28-36) or independent claim 47 (or its dependent claims 48-50).

In view of the above, Applicants respectfully request a withdrawal of the rejections of claims 26-37 and 47-50 under 35 U.S.C. § 102(b) over both Schobel and Wehling.

### **Conclusion**

For the foregoing reasons, it is submitted that all claims are patentable, and a Notice of Allowance is respectfully requested.

No fees are believed due. Any deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

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Respectfully submitted,  
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